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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,615	02/15/2002	Joseph C. Cauthen III	8442.0002-02	2841

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,615

Applicant(s)

CAUTHEN, JOSEPH C.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004 and 14 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12, 15, 16 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 1-7, 14 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/20/04; 8/25/04; 6/8/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 12/2/04 and response to the notice of non-compliant amendment filed 6/14/05 have been entered. The changes to the specification and claims have been approved by the examiner. All pending claims 1-12 and 14-22 are being considered for further examination on the merits.
2. The declaration filed on 12/2/04 under 37 CFR 1.131 is sufficient to overcome the Ferree (USPN 6,245,107) and Bao et al. (USPN 6,224,630) references.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 8-12, 15, 16 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (USPN 5,571,189 as cited in applicant's IDS).

Kuslich discloses a therapeutic device capable of treating a spinal disc annulus having an aperture with all the elements of claim 21. See Figures 4, 5, 8-10 and column 7, lines 8-20 and 41-53 for the device (40) comprising a biocompatible material for placement in (Figure 5) and across (Figure 10) the aperture (46) such that the material forms a bridge (when fill opening 48 is closed by knot 58 shown in Figures 10 and 18). The equatorial band (42) portion of the device

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(40) opposes the annular wall (column 6, lines 62-65) and is made up of multiple layers of the fabric that forms the device (40) (column 10, lines 7-9). See column 7, lines 8-20 for the fabric that forms the device (40) allowing the ingrowth and through-growth of blood vessels and fibrous tissue and bony trabeculae. The equatorial band (42), opposing the annular wall, will therefore inherently provide a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus.

Claims 8 and 9, see column 6, lines 57-60 for the device (40) comprising a bladder (bag) comprising a material enclosing an internal cavity.

Claim 10, see Figure 5 and columns 6-7, lines 67-4 for the internal cavity being empty.

Claim 11, see column 7, lines 21-22 for the material comprising a thin flexible biocompatible material.

Claims 12 and 15, see column 7, lines 8-20 and 40-52 for the material comprising a semi-permeable material or an impermeable material (solid material with perforations added).

Claim 16, see column 7, line 10 for internal cavity containing a biocompatible fluid.

Claim 18, see column 7, line 52 for the device being made from a bioresorbable material.

Claim 19, see column 7, lines 32-39 and 53 for the device comprising a biocompatible fiber mesh.

Claims 20 and 22, see column 7, lines 8-20 for the material facilitating the regeneration of disc tissue. The fabric material provides as means for fixating the device to the annulus because it allows for the ingrowth of fibrous tissue.

Allowable Subject Matter

5. Claims 1-7, 14 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

6. Applicant's arguments filed 12/2/04 have been fully considered but they are not persuasive.

7. Applicant argues that Kuslich removes the entire annulus fibrosus at the entrance bore (46) to provide an opening for delivery of the device (40). The examiner disagrees. While Figure 4 does show the anterior annulus as no longer present, applicant's attention is directed to Figures 10 and 43-46 and columns 10-11, lines 59-9. The entrance bore (46) made in the anterior annulus (30) (column 8, lines 6-7) is repaired using a patch (120) after the device (40) has been implanted and expanded. This clearly suggests that the anterior annulus is not entirely removed. Otherwise, there would be no bore (46) in the annulus (30) to repair with the patch (120).

8. In response to applicant's argument that Kuslich does not teach anywhere in his specification that the implant device (40) is ever used to treat or repair an aperture in the annulus, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in

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a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The equatorial band (42) is shaped and configured to oppose the annular wall and is made up of multiple layers of fabric. When the band (42) is placed adjacent to the bore in the annulus, thereby spanning the bore, it will indeed provide a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus. Because the claims are product claims, it is not required that the Kuslich disclose the device (40) as being used in the same manner as claimed or produce a result as claimed. Because the device of Kuslich is *capable* of performing the required functions and producing the required results, it meets the claim. No *evidence* has been provided to prove otherwise.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

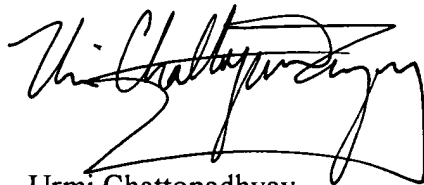
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner